K003250

JAN 2 5 2001

Summary of Safety and Effectiveness

Encore Orthopedics®, Inc.
9800 Metric Blvd
Austin, TX 78758
512-832-9500

Trade Name: FMP Metal/Metal Acetabular Insert

Common Name: Total Hip Prosthesis, Semi-constrained

Classification Name: Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis, 21CFR 888.3358

Description: The acetabular insert consists of polyethylene with a CoCrMo articulating inlay. These components are manufactured from material conforming to ISO 5834/2 and ASTM F799, respectively. The outside geometry of the insert is the same as the acetabular inserts previously cleared under K974093 and K974095 and will mate with the acetabular shells cleared in the above-mentioned submissions. The inner geometry is hemispherical with a tapered area at the mouth. A groove slightly below the mouth accepts a lip on the metal inlay. The metal inlay is attached to the poly by a combination of a taper and locking lip.

The FMP Metal/Metal insert is available with outside diameters of 48mm to 66mm (in 2mm increments) with an inner diameter of 28mm.

Intended Use: The FMP Metal/Metal Acetabular Insert used in total hip is intended for conditions of degenerative joint disease including osteoarthritis and avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedures where other treatments or devices have failed; and treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, which is unmanageable using other techniques.

Comparable Features to Predicate Device(s): Features comparable to predicate devices include same materials, design and indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 5 2001

Ms. Debbie De Los Santos
Regulatory / Clinical Specialist
Encore Orthopedics, Inc.
9800 Metric Boulevard
Austin, Texas 78758

Re: K003250
Trade Name: FMP Metal/Metal Acetabular Insert
Regulatory Class: 3
Product Codes: KWA
Dated: October 12, 2000
Received: October 17, 2000

Dear Ms. De Los Santos:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003250

Device Name: FMP Metal/Metal Acetabular Insert

Indications For Use:

FMP Metal/Metal Acetabular Insert
Indications For Use

Indications for use in total hip replacement include: degenerative joint disease including osteoarthritis and avascular necrosis; rheumatoid arthritis; correction of functional deformity; revision procedures where other treatments or devices have failed; and treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement, which is unmanageable using other techniques.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use ____
(per 21 CFR 801.109)

(Optional Format 1-2-96)_

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003250